REMARKS

Claims 1 and 21-56 remain pending. Claims 27 and 35 are withdrawn from consideration.

Claim Amendments

By this amendment, claims 1, 21, 29, 46-50, 52 and 53 are amended to delete the phrase "other than a copper salicylate complex". An editorial amendment is made in claim 1. No new matter is added by this amendment.

Objection to Specification:

The specification is amended to insert a section entitled "Brief Description of the Drawings".

Applicant will provide the requisite Brief Description in due course.

Rejection under 35 USC 112 (paragraph one)

Claims 50 and 51 stand rejected under 35 USC 112 (paragraph one) as not being enabling for treatment of neoplastic disease. This rejection is respectfully traversed.

In response, applicant submits that the specification contains ample support for the practice of the claimed invention. As one of ordinary skill in the art is

provided with sufficient information to both prepare the claimed composition as well as to administer the compositions in the treatment of neoplastic disease, the rejection is without basis.

It is clear that one of ordinary skill in the art would readily appreciate that there is no reason why the modes of administration for the treatment of neoplastic disease should be any different from the modes of administration for the prevention of such a disease. Thus, if one of ordinary skill in the art wished to prevent neoplastic disease, they would know how to administer the composition to the patient – i.e., the same method would be used as is used to treat the disease. The practice of the claimed invention is neither unpredictable, nor is undue experimentation required.

In view of the above, the rejection is without basis and should be withdrawn.

Rejection under 35 USC 103(a)

Claims 1, 21-26, 28-34, 36, and 46-56 stand rejected under 35 USC 103(a) as being unpatentable over Jackson et al '011 in view of Riley et al '443, Wawretschek et al '741, Verde '257, and Bounous '571. This rejection respectfully is traversed.

Jackson discloses a dietary supplement for supplementing the micronutrient and phytochemical needs of women at various stages of their life cycle to prevent or reduce the risk of a number of conditions, including some types of cancer. The disclosed supplements comprise copper, vitamin C, and thirteen other components, including manganese, iron and zinc, in admixture with a biologically acceptable carrier (see col. 2, line 34 to column 3, line 21). It is noted that none of the compositions comprise sulfur, and there is no teaching of the use of compositions for use in the treatment of neoplastic disease.

Riley is directed to a modular system of multivitamin and mineral supplementation for improving public health by ensuring an adequate intake of micronutrients needed for disease prevention and protection against nutritional losses and deficiencies due to, for example, lifestyle factors and common inadequate dietary patterns. See column 1, lines 20-26. Modules 5 and 6 both comprise copper, aspirin (acetylsalicylic acid), and vitamin C, together with 24 other components, such as iron, manganese and zinc. It is noted that none of the disclosed compositions includes sulfur. Also, while the compositions can be used to help decrease the risk of cancer (see col. 9, lines 30-31), the reference does not teach the actual treatment of cancer using the disclosed compositions.

Wawretschek discloses means of reinforcing the pharmaceutical action of medicaments which exhibit an affinity for linking with blood proteins *in vivo* and

in vitro. It is an object of the invention to find a means which is capable of providing a controlled increase of that portion of the drug to be used which is not bonded to the serum albumen (see column 1, lines 55-58). This is achieved by the use of orotic acid and/or a physiologically tolerable orotic acid salt. The most relevant example appears to be Example 5 in which the analgesic efficacy of sodium salicylate was examined both alone and in binary composition with choline orotate. It is noted that there is no disclosure of the use of copper, vitamin C, manganese, iron, sulfur, or zinc. The reference further fails to suggest the treatment of cancer.

Verde discloses an edible composition which relieves haemorrhoidal symptoms and reduces haemorrhoidal swelling (column 1,lines 59-61). In Example 1, a composition is disclosed consisting essentially of 25 grams of flowers of sulfur, and 75 grams of cream of tartar. Verde does not disclose the use of copper, salicylic acid, vitamin C, manganese, iron or zinc in the compositions. The reference is also silent with respect to the treatment of cancer.

Bounous discloses an oral composition comprising whey protein concentrate in undenatured conformation. The composition has an effect on the immune response, inter alia, to development of chemically induced colon carcinoma (see column 1, lines 21-29). The exemplified composition comprises copper, vitamin C, and 27 other components, including iron and zinc. It is noted

that the composition does not include manganese or sulfur. The composition apparently only increases resistance to colon carcinoma (column 11, line 43), as opposed to being taught as a cancer treating agent.

In support of the rejection, the Examiner apparently seeks to combine various unrelated teachings of the numerous references in an attempt to result in the claimed invention. One of ordinary skill in the could not, in applicant's view, arrive at their invention upon being confronted with the unrelated teachings of the cited references, absent an impermissible hindsight reconstruction of the cited references. Applicant notes, for example, that Wawrctschek and Verde) are silent with respect to the treatment of cancer, while the other cited references are only concerned with the prevention or risk reduction of cancer (as opposed to the treatment of cancer).

While Jackson is apparently believed by the Examiner to be the closest prior art, Jackson does not disclose a composition comprising salicylic acid or a physiologically acceptable derivative thereof. The therapeutic effect of salicylic acid in the present invention is that it is an essential component of the composition thought to promote formation of the enzyme super oxide dismutase (SOD), which functions as a free radical scavenger and reduces DNA damage caused by free radical attack (see page 6, lines 28-30). The problem addressed by the present invention in light of Jackson can accordingly be defined in terms of how to best

promote the formation of SOD to prevent or reduce DNA damaged caused by free radical attack.

Wawretschek discloses sodium salicylate, but only in the context of its analgesic activity. There is no mention of the use of sodium salicylate to promote SOD formation or the treatment of cancer. One of ordinary skill in the art, when considering the above problem, would not consider this reference to address such a problem.

Riley discloses the use of aspirin or bioequivalents thereof, such as salicylic acid (see column 21, lines 48-59), but only in the context of its antiplatelet aggregating capacity (see column 5, lines 35-36). There is no mention in Riley of the use of salicylic acid or a physiologically acceptable salt thereof in a composition to promote the formation of SOD or of its use in the treatment of cancer.

The Examiner's attention is also directed to Martindale, "The Complete Drug Reference, 32nd edition, 1999 at page 18, column 2, lines 14-15, copy attached, which states that non-acetylated salicylates (such as salicylic acid or salts thereof) do not inhibit platelet aggregation. Therefore, in the unlikely event that one of ordinary skill in the art would consider Riley as being pertinent, the use of salicylic acid or a non-acetylated salt thereof is contraindicated by Martindale.

Therefore, one of ordinary skill in the art, when considering the above-mentioned problem, would not consider Riley as it addresses a different problem.

Neither Verde nor Bounous make any mention of the use of salicylic acid (or salts thereof) – thus, the combination of the teachings of Jackson with those of these references does not result in a composition suitable for nor the treatment defined by the claims.

Indeed, the claimed composition provides benefits not otherwise provided by the prior art compositions. For instance, in one embodiment, the claimed composition is tolerated better than an equivalent aspirin-based composition. Aspirin is known to prolong bleeding by inhibiting platelet formation. This process is irreversible. Prolonged use of aspirin should thus be avoided, especially by the elderly, due to the potential for gastro-intestinal bleeding. However, as mentioned above, sodium salicylate does not inhibit platelet aggregation – bleeding time is accordingly not prolonged. A composition containing sodium salicylate can thus be used for a prolonged period of time.

In view of the above, applicants submit that, one of ordinary skill in the art, in the absence of hindsight reconstruction of the references, would not arrive at the claimed invention upon being confronted with the teachings of the cited references. Further, no motivation exists which would permit modification of Jackson to include salicylic acid or a physiologically acceptable salt thereof. In

view of such deficiencies, both the claimed composition and the method of use thereof are neither disclosed nor suggested by the cited prior art.

The rejection is without basis and should be withdrawn.

In view of the above, the application is in condition for allowance, and an early indication of same is earnestly solicited.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Very truly yours,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____

James W. Hellwege
Reg. No. 28,808
P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

Attachment: Martindale, "The Complete Drug Reference, 32nd edition, 1999, pp. 14 and 17-19